Health Canada Santé Canada

Canada

Canadian Adverse Reaction Newsletter

Volume 16 • Issue 2 • April 2006

www.hc-sc.gc.ca/dhp-mps/medeff/bulletin/index_e.html

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Scope

This quarterly publication alerts health professionals to potential signals detected through the review of case reports submitted to Health Canada. It is a useful mechanism to disseminate information on suspected adverse reactions to health products occurring in humans before comprehensive risk–benefit evaluations and regulatory decisions are undertaken. The continuous evaluation of health product safety profiles depends on the quality of your reports.

Reporting Adverse Reactions

Contact Health Canada or a Regional AR Centre free of charge

Phone: 866 234-2345
Fax: 866 678-6789

Form available at:

www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/index_e.html

Tenofovir (Viread) and NSAIDs: acute renal failure

Tenofovir disoproxil fumarate (Viread) is an antiretroviral indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents in patients 18 years of age and older.[1] Tenofovir was approved for use in Canada on Mar. 18, 2003, and was marketed on Mar. 15, 2004. Nephrotoxicity, including renal failure, renal insufficiency, elevated creatinine level, hypophosphatemia and Fanconi syndrome, has been reported with the use of tenofovir in clinical practice, as indicated under warnings and precautions in the product monograph.[1]

From Mar. 18, 2003, to Dec. 1, 2005, Health Canada received 22 domestic reports of adverse reactions suspected of being associated with the use of tenofovir. Ten of these reports involved nephrotoxic reactions, 3 of which were observed when a nonsteroidal anti-inflammatory drug (NSAID) was added along with the antiretroviral therapy, which included tenofovir. A short description of these 3 cases follows:

Case 1: A 53-year-old man with a normal serum creatinine level took tenofovir for 29 months along with other medications. After taking indomethacin (100 mg rectally twice daily) for 5 days to treat polyarthralgias, he experienced rectal bleeding, vomiting, acute renal failure and acute tubular necrosis. The indomethacin and tenofovir were discontinued. The patient required dialysis for 2 months; he had not yet recovered at the time of reporting.

Case 2: A 48-year-old man with a history of hepatitis C, ascites and liver insufficiency took tenofovir for 7 months along with other medications before starting therapy with naproxen (375-mg tablets prescribed 3 times daily). After taking 90 tablets over 2 months, the patient was admitted to hospital with acute renal failure and acute tubular necrosis. He died 3 days later.

Case 3: A 49-year-old man took tenofovir for more than a year with other medications. After 2 months of valdecoxib therapy (20 mg/d) for osteoarthritis, acute renal failure and nephrotic syndrome occurred requiring hospital admission. The valdecoxib was discontinued, all other medications were withheld, and the reaction abated.

Tenofovir is primarily excreted by the kidneys by a combination of glomerular filtration and active tubular secretion.[1] Renal toxicity

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occurs with the accumulation of tenofovir in the proximal tubule and appears to be concentration dependent.[2] Cases of renal failure with tenofovir have been reported in patients with no known risk factors.[1] However, published case reports of nephrotoxicity suggest that there may be specific risk factors for the few patients in whom tenofovir-related nephrotoxicity develops.[2] Risk factors may include pre-existing renal dysfunction, long duration of use, low body weight, concomitant use of drugs that may increase levels of tenofovir (e.g., ritonavir), and other drug interactions.[2-4] Long-standing HIV infection itself may lead to higher incidence of nephropathy.[2]

Concurrent use of a nephrotoxic agent should be avoided with tenofovir, and the dosing interval should be adjusted in patients with a baseline creatinine clearance of less than 50 mL/min.[1] NSAIDs are frequently used and are available over the counter. Since NSAIDs are potentially nephrotoxic, their use during tenofovir therapy may represent an additional risk for renal failure.

Marielle McMorran, BSc, BSc(Pharm)

References

1. *Viread (tenofovir disoproxil fumarate tablets)* [product monograph]. Mississauga (ON): Gilead Sciences Canada, Inc.; 2005.
2. Gupta SK, Eustace JA, Winston JA, et al. Guidelines for the management of chronic kidney disease in HIV-infected patients: recommendations of the HIV Medicine Association of the Infectious Diseases Society of America. *Clin Infect Dis* 2005;40:1559-85.
3. Perazella MA. Drug-induced nephropathy: an update. *Expert Opin Drug Saf* 2005;4(4):689-706.
4. Fine DM. Tenofovir nephrotoxicity — vigilance required [editorial]. *AIDS Read* 2005;15(7):362-3.

Adverse reaction reporting — 2005

The statistics for adverse reaction (AR) reporting for 2005 are presented in a new format to provide additional details. Health Canada received reports of 10 410 new domestic cases of suspected ARs to health products (pharmaceuticals, biologics [e.g., fractionated blood products, and therapeutic and diagnostic vaccines], natural health products and radiopharmaceuticals) in 2005, which were derived from 15 001 reports. The initial report and all subsequent information received as follow-up reports are combined and considered to be one case. Domestic cases were reported for the most part by health professionals, either directly to Health Canada or indirectly through another source (Table 1). A further analysis of the total number of cases by reporter type (originator) is outlined in Table 2. In Canada, Market Authorization Holders (MAHs) of health products are required to submit to Health Canada all reports of serious domestic ARs within 15 days. In addition, MAHs are required to send within 15 days all reports of serious unexpected ARs that have occurred outside Canada (foreign ARs) for the products they sell in other countries as well as in Canada.

Of the domestic cases received, 7223 (69.4%) were classified as serious.

Table 1: Source of domestic cases* of adverse reactions (ARs) received by Health Canada in 2004 and 2005

	No. (%) of cases received			
Source	2004		2005	
Manufacturer	6 114	(59.7)	6 482	(62.3)
Regional AR centre	3 617	(35.3)	3 470	(33.3)
Other†	507	(5.0)	458	(4.4)
Total	10 238	(100.0)	10 410	(100.0)

*Cases result from the merge of initial, follow-up and duplicate reports.
†Includes, but not limited to, professional associations, nursing homes, hospitals, physicians, pharmacists, Health Canada regional inspectors, coroners, dentists and patients.

Table 2: Number of domestic AR cases* by type of reporter (originator) in 2004 and 2005

	No. (%) of cases			
Reporter	2004		2005	
Pharmacist	3 011	(29.4)	2 592	(24.9)
Physician	2 667	(26.2)	2 970	(28.5)
Health professional†	1 499	(14.6)	1 267	(12.2)
Consumer/ patient	1 928	(18.8)	2 304	(22.1)
Nurse	873	(8.5)	926	(8.9)
Other	260	(2.5)	351	(3.4)
Total	10 238	(100.0)	10 410	(100.0)

*Cases result from the merge of initial, follow-up and duplicate reports.
†Type not specified in report.

In the Food and Drugs Act and Regulations, a serious AR is defined as "a noxious and unintended response to a drug which occurs at any dose and requires inpatient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death." A serious unexpected AR is defined as "a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug."

The reporting of domestic ARs in Canada has increased steadily over the past 7 years, with 1.7% more cases in 2005 than in 2004 (Fig. 1).

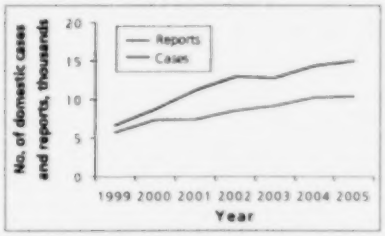

Fig. 1: Number of domestic reports and cases of adverse reactions (ARs) received by Health Canada from 1999 to 2005. (Reports include follow-up, duplicate and unenterable reports. Cases result from the merge of initial, follow-up and duplicate reports.)

Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

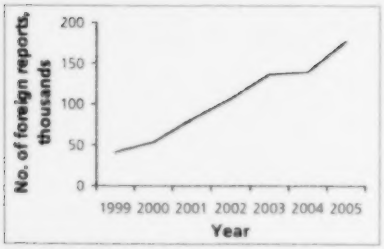

Fig. 2: Number of foreign AR reports received by Health Canada from 1999 to 2005. (Reports include follow-up, duplicate and unenterable reports.)

Health Canada also received 176 448 reports of foreign ARs in 2005, a greater than 4-fold increase since 1999 (Fig. 2). Because of this volume and the capacity of the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) database, foreign reports are not included in the domestic AR database.

Health Canada would like to thank all who have contributed to the program and encourages the continued support of postmarketing surveillance through AR reporting. ARs may be reported by using the toll free telephone (866 234-2345) and fax (866 678-6789) lines. Incidents involving medical devices are not collected in the CADRMP database and should be reported toll free through the Inspectorate Hot Line (800 267-9675).

Bill Wilson, BSc, BA, Health Canada

Isotretinoin (Accutane): myocardial infarction, cerebrovascular and thromboembolic disorders

Isotretinoin (Accutane) has been marketed in Canada since 1983 and is indicated for the treatment of severe nodular and inflammatory acne, acne conglobata and recalcitrant acne.[1]

From the date of marketing to Dec. 31, 2005, Health Canada received 29 domestic reports of vascular disorders or myocardial infarction suspected of being associated with the use of isotretinoin. Table 1 summarizes the 11 reports of stroke, thromboembolic disorders and myocardial infarction, all of which are not labelled adverse reactions (ARs) in the Canadian product monograph.[1] One report (case 8) provided laboratory test results for familial thrombophilias, lupus anticoagulant, anticardiolipin and anti-beta$_2$ glycoprotein antibodies, all of which were negative. Another report (case 10) indicated a positive result for lupus anticoagulant.

Health care professionals are encouraged to report any cases of myocardial infarction, cerebrovascular and thromboembolic disorders suspected of being associated with isotretinoin.

Pascale Springuel, BPharm, RAC; Gilbert Roy, BPharm, Health Canada

Table 1: Summary of reports submitted to Health Canada of myocardial infarction, cerebrovascular and thromboembolic disorders suspected of being associated with isotretinoin, from date marketed in Canada to Dec. 31, 2005*

Case	Reported reaction†	Age/Sex	Dose, mg‡	Time to onset§	Outcome¶	Risk factors or concomitant medical conditions
1	Myocardial infarction	25/M	80	4 mo**	Unknown	No known cardiac risk factors or family history
2	Stroke	18/M	60	2 mo	Recovered	None reported
3	Stroke	20/M	60	4 d	Recovered	Headache with visual disturbances, smoker. History of Raynaud syndrome, scleroderma, asthma, aphthae
4	Stroke	26/F	–	2 mo	Recovered	Hypertension
5	Cerebrovascular disorder	28/F	40	3 wk	Recovered	History of migraine
6	Cerebrovascular disorder	29/F	70	2 mo	Recovered	Hypertension, migraine, hypoglycemia with blackouts, cerebral hemorrhage (4 yr earlier)
7	Pulmonary embolism	20/F	50	3 mo	Recovered	Oral contraceptives
8	Pulmonary embolism	26/F	40	2 wk	Recovered	Obesity, hypertension, history of pulmonary embolism with isotretinoin + oral contraceptives 2.5 yr earlier
9	Thrombophlebitis	37/F	40	53 d	Recovered with sequelae	None reported
10	Hepatic vein thrombosis	15/M	40	Unknown	Not yet recovered	Diabetic, hypertension, antiphospholipid syndrome
11	Thrombosis	48/F	40	4 mo††	Unknown	None reported

***These data cannot be used to determine the incidence of adverse reactions (ARs) because ARs are underreported and neither patient exposure nor the amount of time the drug was on the market has been taken into consideration.**
†According to the *World Health Organization Adverse Reaction Terminology* (WHOART).
‡Average daily dose taken at the time of the AR, as indicated by the reporter.
§Estimated from the beginning of the treatment.
¶At the time of reporting, as indicated by the reporter.
**Within 5 weeks after a dose increase from 40 to 80 mg.
††Approximately 2 months following isotretinoin discontinuation.

Reference

1. *Accutane (isotretinoin)* [product monograph]. Mississauga (ON): Hoffmann-La Roche Limited; 2005.

Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Case presentation

Recent Canadian cases are selected based on their seriousness, frequency of occurrence or the fact that the reactions are unexpected. Case presentations are considered suspicions and are presented to stimulate reporting of similar suspected adverse reactions.

Acanthamoeba keratitis and overnight orthokeratology

In Canada, contact lenses are regulated as medical devices. Health Canada received a report of *Acanthamoeba* keratitis suspected of being associated with contact lenses worn for the purpose of orthokeratology (OK). OK is defined as the transient reduction in myopia through the use of a series of increasingly flat, reverse geometry, rigid, gas-permeable contact lenses that temporarily reduce the central curvature of the cornea.[1] Patients wear the contact lenses overnight.[1]

A myopic 12-year-old boy was fitted with Boston XO contact lenses for overnight OK. About 18 months later, he reported a sore right eye to the optometrist. After 1 week of treatment with an antiviral agent, the patient was seen by a local ophthalmologist for further care. Microbiologic testing identified *Acanthamoeba* species in cultures from both corneal scrapings and the contact lens. The patient reported following the office-recommended lens cleaning and disinfecting protocol with the commercially available solutions. At the time of reporting, the patient had not yet recovered.

Protozoan infections from *Acanthamoeba* are severe but rare in conventional use of rigid contact lenses and have been linked to contamination from water sources.[2] Published reports of acanthamebic keratitis in OK patients indicate that corneal scarring caused by these infections may necessitate corneal transplantation in affected patients.[1,3] Health Canada encourages health care professionals to report this sight-threatening complication of OK[1] that affects mostly teenagers,[3] as well as other adverse incidents involving contact lenses or other medical devices to the Health Products and Food Branch Inspectorate through the toll free hot line (800 267-9675).

References

1. Yepes N, Lee SB, Hill V, et al. Infectious keratitis after overnight orthokeratology in Canada. *Cornea* 2005; 24(7):857-60.
2. Watt K, Swarbrick HA. Microbial keratitis in overnight orthokeratology: review of the first 50 cases. *Eye Contact Lens* 2005;31(5):201-8.
3. Wilhelmus KR. Acanthamoeba keratitis during orthokeratology. *Cornea* 2005;24(7):864-6.

Summary of health professional and consumer advisories posted from Nov. 16, 2005, to Feb. 17, 2006
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Date	Product	Subject and type
Feb 16 & Dec 19	Tequin	Serious hypoglycemia and hyperglycemia — consumer information — consumer information and health professional communication — Bristol-Myers Squibb Canada
Feb 9	Chinese herbal products	Potential health risks — consumer information
Feb 7	Ketek	Liver failure — consumer information
Feb 6	Methyl-1-testosterone	Warning not to use methyl-1-testosterone — consumer information
Feb 1	White Peony	Warning not to use White Peony scar-repairing pills — consumer information
Jan 31 & 12	Blood lancing devices	Transmission of blood-borne diseases — consumer information and notice to hospitals
Jan 26	Octreotide Acetate Omega	Recall of Octreotide Acetate Omega 500 µg/mL — consumer information and health professional communication
Jan 26	Libidfit	Warning not to use Libidfit — consumer information
Jan 24	WinRho SDF	Intravascular hemolysis — Cangene Corporation — consumer information and notice to hospitals
Jan 21	Pacemakers	Important safety information — Guidant Canada Corporation — health professional communication
Jan 19	M2 Formula and Energy 2000	Warning not to use M2 Formula and Energy 2000 — consumer information

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References

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Summary of advisories continued from previous page

Date	Product	Subject and type
Jan 13	Enbrel, Humira and Remicade	Hepatitis B virus (HBV) reactivation — Amgen Canada, Inc., Abbott Laboratories, Ltd. and Schering Canada, Inc. — consumer information and health professional communication
Jan 12	Macugen	Hypersensitivity reactions — Pfizer Canada Inc. — consumer information and health professional communication
Jan	Blood Glucose Monitors	Important safety information — Becton Dickinson and Company — consumer information
Dec 28	Medical telemetry systems	Risk of electromagnetic interference — notice to hospitals
Dec 28	Linvatec surgical handpieces	Important safety information — notice to hospitals
Dec 28	Kaizen Ephedrine HCL	Advisory not to use Kaizen Ephedrine HCL tablets — consumer information
Dec 23	Tamiflu	Advisory to be cautious when buying Tamiflu online — consumer information
Dec 22 & 16	Paxil	Increased risk of cardiac defects following exposure during first trimester of pregnancy — GlaxoSmithKline Inc. — consumer information and health professional communication
Dec 21	Chaparral	Warning not to take products containing chaparral — consumer information
Dec 20 & 19	Avandia and Avandamet	New onset and/or worsening of macular edema — GlaxoSmithKline Inc. — consumer information and health professional communication
Dec 19	Implantable medical devices	Update: interactions — notice to hospitals
Dec 16	Bextra	Health Canada prohibits sale of Bextra in Canada — consumer information
Dec 15	Colleague pump	Important safety information — Baxter Corporation — health professional communication
Dec 7	Zevalin	Severe mucocutaneous reactions — Berlex Canada Inc. — consumer information and notice to hospitals
Dec 2	Pms-Sodium Phosphates oral solution	Kidney impairment and nephrocalcinosis — Pharmascience Inc. — consumer information and health professional communication
Dec 2	Fleet Phospho-Soda	Kidney impairment and nephrocalcinosis — Johnson & Johnson, Merck Consumer Pharmaceuticals — consumer information and health professional communication
Dec 2	Euro-ASA 80 mg	Warning to return bottles of Euro-ASA 80 mg chewable tablets — consumer information
Nov 30	Sigma series pacemakers	Important safety information — Medtronic of Canada Ltd. — health professional communication
Nov 28	Evra	Warning: clarification on status of Evra — consumer information
Nov 25	Aranesp	Pure red cell aplasia — Amgen Canada Inc. — consumer information and health professional communication
Nov 24 & 17	Femara	Contraindication in premenopausal women — Novartis Pharmaceuticals Canada Inc. — consumer information and health professional communication
Nov 23	Climacteron injection	Discontinuation of Climacteron injection — Sandoz Canada Inc. — health professional communication
Nov 21	Infusion pumps	Product recall: Baxter/Sabratek 6060 pumps — Baxter Corporation — health professional communication
Nov 18	GenTeal Gel	Warning not to use certain lots of GenTeal Gel — consumer information
Nov 18	Aquify comfort drops	Warning not to use certain lot of Aquify 2-ml long-lasting comfort drops — consumer information
Nov 17	Shortclean	Warning not to take the Chinese medicine Shortclean — consumer information
Nov 14 & 9	Accu-Chek Aviva	Safety information: Accu-Chek Aviva glucose monitors — Roche Diagnostics — consumer information and health professional communication

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Regional Adverse Reaction Centres: relocation

Health Canada announces the relocation of the Regional Adverse Reaction (AR) Centres in British Columbia, Saskatchewan, Ontario, Quebec and Atlantic Canada to the Regional Offices of the Health Products and Food Branch of Health Canada effective Apr. 1, 2006. The Regional AR Centres in Alberta and Manitoba were opened in April 2005 in Health Canada Regional Offices, and their location therefore will not change. The Regional AR Centres will be aligned with the Health Canada regions and will provide regional coverage for all provinces and territories.

To report a suspected AR to health products marketed in Canada, health professionals and consumers should telephone toll free (866 234-2345) or complete a copy of the AR Reporting Form and forward it to the appropriate Regional AR Centre or the National AR Centre by mail or by fax toll free (866 678-6789). Copies of the form are available from your Regional AR Centre or the National AR Centre, and the Canadian *Compendium of Pharmaceuticals and Specialties* (CPS).

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Canadian Adverse Reaction Newsletter

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Acknowledgements
Expert Advisory Committee on Pharmacovigilance, Regional AR Centres and Health Canada staff

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ISSN 1499-9447, Cat no H42-4/1-16-2E

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and Effectiveness Information
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Canadian Adverse Reaction Newsletter

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Acknowledgements

Expert Advisory Committee on Pharmacovigilance,
Regional AR Centres and Health Canada staff

Suggestions?

Your comments are important to us.
Let us know what you think by reaching us
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ISSN 1499-9447, Cat no H42-4/1-16-2E

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Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.